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EXAMINER
DEJONG, ERIC S

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/057,431	MORTENSEN, PETER PAASCH	
	Examiner	Art Unit	
	Eric S. DeJong	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 November 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,14-20,28,44 and 47-53* is/are pending in the application.

4a) Of the above claim(s) *28,50 and 51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-20,44,47-49,52 and 53* is/are rejected.

7)☒ Claim(s) *49-53* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *01/15/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED OFFICE ACTION

Applicants' response filed 11/14/2007 is acknowledged.

Claim Misnumbered

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 50-54 have been renumbered as claims 49-53, respectively. Appropriate correction is required.

Claims 13, 21-27, 29-43, 45, and 46 are canceled. Claim 28 is withdrawn as being directed to the non-elected invention of Group II (see response, filed 04/12/2004).

Newly submitted claims 50 and 51 (misnumbered as claims 51 and 52, respectively) are directed to an invention that is independent or distinct from the invention originally claimed for the following reasons:

The originally elected invention of Group I is drawn to methods of fluorescence analysis (see the Restriction requirement mailed 03/19/2004). The non-elected invention of Group II is drawn to a granulation or coating apparatus. Newly presented claims 50 and 51 (misnumbered as claim 51 and 52, respectively) are drawn to a

process comprising making a granular composition comprising a granulation apparatus of Group II (see lines 4 and 5 of claim 50 and lines 4-6 of claim 51). Therefore, newly presented claims 50 and 51 are directed to a distinct process than that of the elected Group I because it involves both the process of making (not previously presented) and a granulation apparatus from the non-elected invention of Group II.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 50 and 51 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Claims 1-12, 14-20, 44, 47-49, 52, and 53 are pending and currently under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 01/15/2007 is acknowledged. Accordingly, the information disclosure statement has been considered by the examiner.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-12, 14-20, 44, 47-49, 52, and 53 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. This rejection is newly applied.

Claims 1-12, 14-20, 44, 47-49, 52, and 53 are drawn to methods of fluorescence analysis. The recited processes involve obtaining data on emitted light from a first granular composition, illuminating a second granular composition, detecting emitting light, and predicting the amount of fluorescent marker from the second granular composition and, therefore, involves the application of a judicial exception. Regarding inventions involving the application of a judicial exception, said application must be a practical application of the judicial exception that includes either a step of a physical transformation, or produces a useful, concrete, and tangible result (State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998), AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)). In the instant claims, there is no step of physical transformation that results from said application of judicial exception and, further, the recited process step of illuminating a granular composition does not result in a physical transformation, thus the Examiner must determine if said application of a judicial exception produces a useful, concrete, and tangible result.

Claims 1-12, 14-20, 44, 47-49, 52, and 53 do not produce a tangible result. A tangible result requires that the claim must set forth a practical application of a judicial exception to produce a real-world result . The result of the instant claims is a prediction of the amount of fluorescent marker or an estimation of a quality parameter, which are not further displayed or output to a practitioner of the recited methods. Examples of statutory processes include those methods that further recite a final step of outputting a result (in the instant case a prediction of the amount of fluorescent marker or an estimation of a quality parameter) to a user or to a display.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-12, 14-20, 44, 47-49, 52, and 53 are rejected under 35 U.S.C. 102(e)(2) as being anticipated by Chandler et al. (US Patent No. 6,268,222).

The instant claims are drawn to a method of fluorescence analysis comprising illuminating a granular composition comprising a purified biologically active compound containing a fluorescent marker, detecting light emitted from the fluorescent marker, and predicting the amount of fluorescent marker in the granular composition. The prediction

of the amount of fluorescent marker in the granular composition is accomplished by comparing the light emitted therefrom to data on light emitted from a known granular composition.

Chandler et al. sets forth the development and applications of novel fluorescent articles comprising a core particle region having on its surface a plurality of smaller polymeric particles stained with different fluorescent dyes (see Chandler et al., Abstract and throughout), which reads on a first and second granular composition comprising a core and a layer capable of fluorescence emission as recited in claim 1. Chandler et al. further discloses methods for detecting multiple subpopulations of analytes of interest employing a fluorescent, complementary binding moiety to each of said analytes, wherein each analyte and its complementary binding moiety comprise first and second members of a specific binging pair (see Chandler et al., col. 15, line 38 through col. 16, line 44). The disclosed method includes the steps of forming a mixture of the fluorescently labeled moieties of the binding pair, contacting the mixture and a solid support so that specific binding pairs are formed on solid supports, and relating the presence and concentrations of the analytes of interest in the sample by means of observing and quantifying a resultant fluorescence signal (see Chandler et al., col. 4, line 51 through col. 5, line 42 and Examples 1-11 at col. 16, line 55 through col. 24, line 53), which reads on detecting and obtaining data on emitted light from a first and second granular composition as recited in claim 1. Further, Examples 1 and 3 of Chandler et al. further sets forth an embodiment of the disclosed invention wherein different microparticle samples were stained with a predetermined amount of different

fluorescent dyes, which reads on a first granular composition having known quality parameters as recited in claim 1. The different microparticle samples were further mixed together at different ratios to form a new series of samples, which reads on a second granular composition as recited in claim 1 and. Treating this ratio as an unknown, Chandler et al. sets forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles, which reads on predicting the amount of fluorescent marker of the second granular composition as recited in claim 1, a prediction including comparing light from a second composition to that of the first known composition as recited in claim 10, and a prediction made in real time as recited in claim 11. The fluorescence intensity measured from each of the new series of samples allowed for the determination and back calculation of the particular ratio of different microparticles, which reads on changing at least one process parameter as a result the fluorescence analysis as recited in claim 49. Therefore, Chandler et al. further anticipates the method of claim 44 in the above example by demonstration of a calibration model from granular compositions of known quality that, by comparative means, are used to evaluate the quality of samples of unknown quality. The disclosed fluorescent particles range from 0.1 to 1,000 μM in diameter (see Chandler et al., col. 3, lines 9-20), which reads on a first and second granular composition having an average size between 20-2000 μM as recited in claim 20.

Chandler et al. further discloses that the composition of the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents and to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64) that allow for interaction with and, subsequently, the detection of antigens, proteins, enzymes, and other biological molecules (see Chandler et al., col. 3, lines 56-62 and col. 4, lines 45-50), which reads on granular compositions comprising a purified enzyme as recited in claims 1 and 44, a homogenous substantially continuous layer of purified enzyme disposed on a core as recited in claims 19 and 47, an enzyme bio-catalyst or therapeutic agent as recited in claim 12, granular compositions that further comprise auxiliary granulation agents as recited in claims 15-18, and a second granular composition comprising a binder as recited in claim 53. Chandler et al. further teaches the use of a fluorescent polymeric article comprising a coating of fluorescent dye labeled particles and that said article can further be coated or surrounded by a polymeric shell that does not interfere with fluorescent light absorption or emission (see Chandler et al., col. 12, lines 5-19), which reads on a coating agent disposed on the purified enzyme and a coating agent that forms continuous layer around the granule as recited in claims 1 and 44 and a continuous layer of the second granular composition that is substantially enzyme free as recited in claim 52. Further, Example 11 of Chandler et al. teaches specific embodiments of enzymes for use with the disclosed micro/nanoparticles that are hydrolases and oxidoreductases, which reads on the enzyme is a hydrolase or oxidoreductase as recited in claim 14. The fluorescent particles are further disclosed as being capable of emitting a single fluorescence

emission or multiple fluorescence emissions with emission spectra ranging from 450 nm to 1000 nm (see Chandler et al., col. 4, lines 15-30), which reads on the emitted light of 1-10 discrete monochromatic wavelengths as recited in claim 5 and 6. Further, fluorophores that emit light at and above 450 nm are inherently excited to fluoresce by sources of ultraviolet light in the range of 10-350 nm as recited in claims 2-4. The detection means disclosed for observing and measuring fluorescence emissions includes, digital cameras (CCD) as well as other means for converting observed light into digital signals and two-dimensional images (see Chandler et al., col. 4, line 59 through col. 5, line 4), which reads on the at least one detector and at least two detectors as set forth in claims 7-9 and converting emitted light into an electronic signal as recited in claims 44 and 48.

Response to Arguments

Applicant's arguments filed 11/14/2007 have been fully considered but they are not persuasive.

Applicants argue that Chandler et al. does not describe a granular coating having a core and a layer of purified enzyme disposed thereon and a coating agent. Applicants further acknowledged that Chandler et al. the use of fluorescent articles may have a shell.

In response, it is first noted that the instant claims have been amended to recite the limitation of "a coating agent disposed upon the purified enzyme, wherein the

coating agent forms a continuous layer around the granule" (see for example claim 1, lines 3,4, 7, and 8).

It is reiterated from the above rejection that Chandler et al. discloses embodiments wherein the particles may comprise cross-linking agents allowing for the coupling of reactive surfactant agents and to biological materials including enzymes (see Chandler et al., col. 12, lines 58-64) that allow for interaction with and, subsequently, the detection of antigens, proteins, enzymes, and other biological molecules (see Chandler et al., col. 3, lines 56-62 and col. 4, lines 45-50). It is further reiterated from the above rejection that Chandler et al. teaches the use of a fluorescent polymeric article comprising a coating of fluorescent dye labeled particles and that said article can further be coated or surrounded by a polymeric shell that does not interfere with fluorescent light absorption or emission (see Chandler et al., col. 12, lines 5-19). The polymeric shell is further taught as not interfering with fluorescent light emission and absorption.

Therefore, Chandler et al. teaches dye labeled particles that comprise an enzyme layer and that these particles may be attached to a larger polymeric article that is further completely surrounded by a polymeric shell. In this embodiment, all dye labeled particles attached to the larger particle are completely surrounded by said polymeric shell. Therefore, it is maintained that Chandler et al. anticipates the newly recited limitation of a coating agent disposed upon the purified enzyme, wherein the coating agent forms a continuous layer around the granule.

Applicants further argue that chandler et al. does not teach predicting fluorescent marker in the second granulation composition by comparing the amount of emitted light from the fluorescent marker with the data on emitted light from the first granular composition as instantly claimed.

In response, it is reiterated from the above rejection that Chandler et al. sets forth the empirical determination of the ratio of different microparticles based on the comparison to known data regarding the relationship between a particular microparticle concentration and the fluorescence intensity of the specific fluorescent dye used to stain each original collection of microparticles, which reads on predicting the amount of fluorescent marker of the second granular composition.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. DeJong whose telephone number is (571) 272-6099. The examiner can normally be reached on 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Moran Marjorie can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric S DeJong
Examiner
Art Unit 1631

02/01/2008